10/526820
06 Jun 06

WWR:jam 6/6/06 522226 E-223-2002/0-US-03
PATENT

Attorney Reference Number 4239-66646-06
Application Number 10/526,820

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Joel Moss et al.
Application No.: 10/526,820
Filed: March 3, 2005
Confirmation No.: 5471
For: FACTORS THAT BIND INTESTINAL TOXINS
Examiner: To be assigned
Art Unit: 1617
Attorney Reference No.: 4239-66646-06

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: MAIL STOP 16, DIRECTOR OF THE U.S. PATENT AND TRADEMARK OFFICE, P.O. Box 1450, Alexandra, VA 22313-1450 on the date shown below.

Attorney or Agent for Applicant(s) _____

Date Mailed June 6, 2006

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REQUEST FOR REFUND UNDER 37 C.F.R. § 1.26

Applicants hereby request a refund of $1,250.00 for the excess claims fees improperly charged by the U.S. Patent and Trademark Office (USPTO) to Deposit Account No. 02-4550 in connection with the above-referenced application.

The amount of $1,350.00 was charged to Deposit Account No. 02-4550 on November 8, 2005, as shown in a highlighted manner on the attached November 30, 2005 Deposit Account Statement (**Exhibit A**). It appears that this charge is for extra claims fees for the application. This charge is erroneous in view of the following facts:

Applicants filed this application on March 3, 2005, with a Preliminary Amendment to reduce the number of claims, among other things. A copy of the original patent application Transmittal Letter showing the total number of claims filed with this application is attached as **Exhibit B**. A copy of the Preliminary Amendment filed with the application, showing amendments to the claims, is attached as **Exhibit C.** It appears that the filing fees were

calculated by the USPTO **prior** to entry of the Preliminary Amendment, and thus the charge to the deposit account was incorrectly made. As indicated on the Transmittal Letter, this application was amended upon filing to include 49 total claims and three independent claims. Therefore, the filing fee submitted with the application ($2,750.00 plus $40.00 recordation fee, totaling $2,790.00) is correct. No additional charges were required. Applicants therefore request a refund of the miscalculation of claims fees, totaling $1,350.00.

Please mail the refund to the undersigned agent, or credit the refund to Deposit Account No. 02-4550. A copy of this document or paper is enclosed.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By _____
Wayne W. Rupert
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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A NATIONAL STAGE FILING UNDER 35 U.S.C. § 371		ATTORNEY'S DOCKET NUMBER 4239-66646-06 U.S. APPLICATION NO. (If known, see 37 C.F.R. § 1.5) Not yet assigned
INTERNATIONAL APPLICATION NO. PCT/US2003/028282	INTERNATIONAL FILING DATE September 9, 2003	PRIORITY DATE CLAIMED September 10, 2002

TITLE OF INVENTION
FACTORS THAT BIND INTESTINAL TOXINS

APPLICANT(S) FOR DO/EO/US
Joel Moss and Masatoshi Noda

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. § 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. § 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. § 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. § 371(b) and PCT Articles 22 and 39(1). Items 5, 6, 9 and 21 indicated below are submitted to make this express request.
4. ☒ The United States has been elected in a Demand for International Preliminary Examination (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. § 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English-language translation of the International Application (35 U.S.C. § 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau to the United States Receiving Office).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ An English-language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. § 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. § 371(c)(4)).
10. ☐ An English-language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. § 371(c)(5)).

Items 11 to 21 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. §§ 3.28 and 3.31 and the Recordal fee of $40.00 are included.
13. ☒ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 C.F.R. § 1.76.
15. ☐ A substitute specification.
16. ☒ Powers of attorney from the inventors.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 37 C.F.R. §§ 1.821 - 1.825.
18. ☒ A second copy of the published International Application under 35 U.S.C. § 154(d)(4).
19. ☐ A second copy of the English-language translation of the international application under 35 U.S.C. § 154(d)(4).
20. ☒ Other items or information:
    - ☒ Abstract on a separate page.
    - ☐ Written Opinion.
    - ☒ Preliminary Examination Report.
    - ☒ International Search Report.
    - ☒ Copy of Reference Cited.

EV510808334US

SAS:gte 03/03/05 4239-66646-06 360165.doc

EXPRESS MAIL LABEL NO. EV510808334US
DATE OF DEPOSIT: March 3, 2005

U.S. APPLICATION NO. (If known, see 37 C.F.R. § 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
Not yet assigned	PCT/US2003/028282	4239-66646-06

The following fees are submitted:		
21. ☒ Basic national fee $300	$ 300.00	
22. ☒ Examination fee If international preliminary examination report prepared by USPTO and all claims satisfy novelty, nonobviousness (inventive step) and utility (industrial applicability) i.e., provisions of PCT Article 33(1)-(4) ..... $100 All other situations $200	$ 100.00	
23. ☒ Search fee Search fee (37 C.F.R. 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... $100 International Search Report prepared and provided to the Office ..... $400 All other situations $500	$ 100.00	
TOTAL OF 21, 22, and 23 =	$ 500.00	
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in electronic medium). The fee is $250 for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
62 - 100	0 / 50 =	0	x $250	$ 0.00	
Surcharge of $130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 C.F.R. § 1.492(e)).				$ 0.00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	49 - 20 =	29	x $50.00	$ 1,450.00	
Independent Claims	7 - 3 =	4	x $200.00	$ 800.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $360.00	$ 0.00	
TOTAL OF ABOVE CALCULATIONS =				$ 2,750.00	
☐ Reduction of 1/2 for filing by small entity. Small entity status is claimed for this application.				$ 0.00	
SUBTOTAL =				$ 2,750.00	
Processing fee of $130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 C.F.R. §§ 1.492(f)). +				$ 0.00	
TOTAL NATIONAL FEE =				$ 2,750.00	
Fee for recording the enclosed assignment (37 C.F.R. § 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. §§ 3.28, 3.31). $40.00 per property. +				$ 40.00	
TOTAL FEES ENCLOSED =				$ 2,790.00	
				Amount to be refunded	$
				Amount to be charged	$

a. ☒ A check in the amount of $ 2,790.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Director is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 02-4550. A duplicate copy of this sheet is enclosed.

d. ☒ Please return the enclosed postcard to confirm that the items listed above have been received.

NOTE: Where an appropriate time limit under 37 C.F.R. § 1.494 or § 1.495 has not been met, a petition to revive (37 C.F.R. § 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO THE ADDRESS ASSOCIATED WITH

CUSTOMER NUMBER 36218

KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, OR 97204-2988

SIGNATURE

Susan Alpert Siegel, Ph.D.
NAME

43,121
REGISTRATION NUMBER

cc: Docketing

EXPRESS MAIL LABEL NO. EV510808334US
DATE OF DEPOSIT: March 3, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Moss *et al.*
Application No. Not yet assigned
Filed: Herewith
Confirmation No. Not yet assigned
For: FACTORS THAT BIND INTESTINAL TOXINS
Examiner: Not yet assigned
Art Unit: Not yet assigned
Attorney Reference No. 4239-66646-06

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as Express Mail Label No. EV510808334US in an envelope addressed to: MAIL STOP PCT, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Agent for Applicant(s)

Date Mailed March 3, 2005

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COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

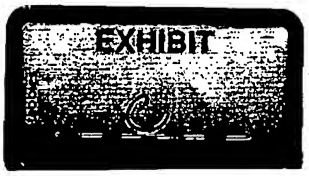
PRELIMINARY AMENDMENT

Prior to examination of the above-referenced patent application, please amend the application as follows:

Amendments to the Specification begin on page 2.

Amendments to the Claims are reflected in the listing of claims, which begins on page 3.

Remarks begin on page 12.



Amendments to the Specification

Please replace the paragraph beginning at page 1, line 3, immediately following the title, with the following rewritten paragraph:

--PRIORITY CLAIM

This is the § 371 U.S. National Stage of International Application No. PCT/US2003/028282, filed September 9, 2003, which was published in English under PCT Article 21(2), which in turn claims the benefit of U.S. Provisional Application No. 60/409,742, filed September 10, 2002, which is incorporated by reference in its entirety.--

Please insert the attached Abstract as page 43 of the specification.

EXPRESS MAIL LABEL NO. EV510808334US
DATE OF DEPOSIT: March 3, 2005

Claims

1. (original) A method for treating a subject having an infection caused by an Stx-producing organism by administering to the subject a therapeutically effective amount of hop bract tannin.

2. (original) The method of claim 1 further comprising administering to the subject a therapeutically effective amount of an antibiotic, the antibiotic being effective to treat an infection with the Stx-producing organism.

3. (original) The method of claim 2, wherein the antibiotic is selected from the group consisting of cefixime, tetracycline, ciprofloxacin, co-trimoxazole, norfloxacin, ofloxacin, fosfomycin and kanamycin and combinations thereof.

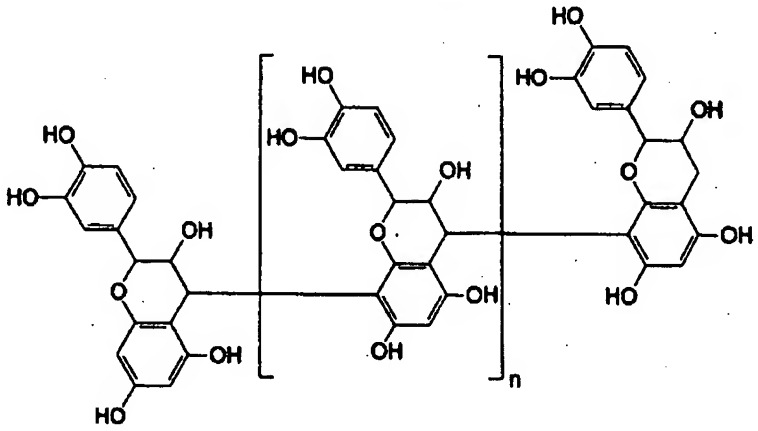
4. (original) The method of claim 1, wherein the hop bract tannin comprises a catechin polymer.

5. (original) The method of claim 4, wherein the catechin polymer comprises a polycatechin between a 10-mer and a 30-mer.

6. (original) The method of claim 1, wherein the infection is an enteric infection.

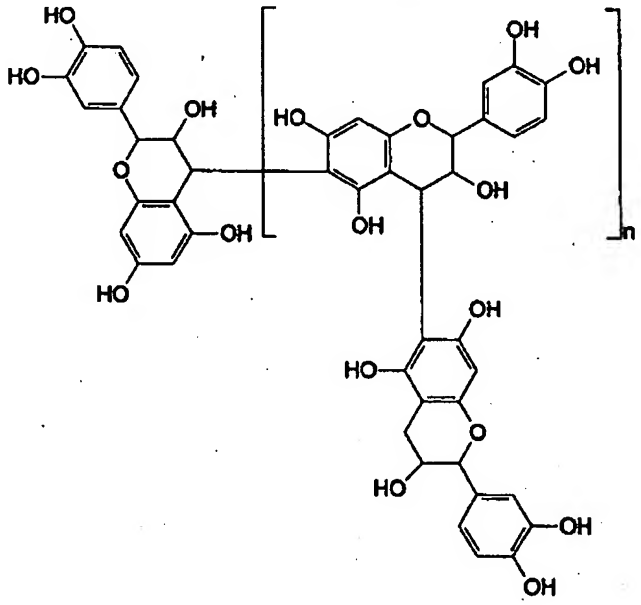
7. (original) The method of claim 6, wherein the hop bract tannin is administered enterically.

8. (original) The method of claim 5 where the polycatechin has the formula



where n=8 to 28.

9. (original) The method of claim 5 where the polycatechin has the formula



where n = 8 to 28.

10. (original) The method of claim 1, wherein the hop bract tannin comprises a fraction isolated from a hop bract extract.

11. (original) The method of claim 10, wherein the fraction has a weight-average molecular mass between 5kDa and 30 kDa.

12. (original) The method of claim 1, wherein the Stx-producing organism comprises an Stx1-producing organism.

13. (original) The method of claim 1, wherein the Stx-producing organism is a Shiga toxin-producing *Eschericia coli.*

14. (original) The method of claim 1, wherein the infection is an enteric infection, and the hop bract tannin comprises a polycatechin between a 10-mer and a 30-mer, which is administered enterically.

15. (original) The method of claim 14, wherein the infection presents clinically as severe diarrhea, hemorrhagic colitis, hemolytic uremic syndrome and thrombotic thrombocytopenic purpura.

16. (canceled)

17. (currently amended) ~~A method of treating a subject having an infection of an Stx-producing organism, comprising~~ The method of claim 1, wherein administering to the subject a therapeutically effective amount of hop bract tannin comprises:

selecting a hop bract tannin having an affinity for an Stx produced by the Stx-producing organism; and

administering the hop bract tannin to the subject enterically in an amount effective to alleviate a clinical presentation of the infection.

18. (original) The method of claim 17, wherein selecting comprises isolating hop bract tannin from a hop bract extract by affinity chromatography with a chromatographic matrix derivatized with the Stx.

19. (original) The method of claim 17, wherein selecting comprises obtaining a high molecular weight fraction of a hop bract extract.

20. (original) The method of claim 19, wherein the high molecular weight fraction has a weight-average molecular weight of 5 kDa or greater.

21. (original) The method of claim 17, wherein selecting comprises detecting a hop bract tannin component having an affinity for the Stx.

22. (currently amended) The method of claim 21, wherein detecting a component having an affinity for the Stx comprises detecting a signal generated by a biosensor, the biosensor having a hop bract tannin as ~~the~~ a bioreceptor portion of the biosensor.

23. (original) The method of claim 22 where the hop bract tannin is a polycatechin.

24. (original) The method of claim 23 where the polycatechin is between a 10-mer and a 30-mer polycatechin.

25. - 26. (canceled)

27. (original) The method of claim 17, wherein the clinical presentation of the infection is one or more of severe diarrhea, hemorrhagic colitis, hemolytic uremic syndrome and thrombotic thrombocytopenic purpura.

28. (canceled)

29. (original) A method for detecting the presence of an Stx in a biological sample, comprising:

contacting the biological sample with a hop bract tannin; and

detecting a macromolecular complex between the Stx and the hop bract tannin.

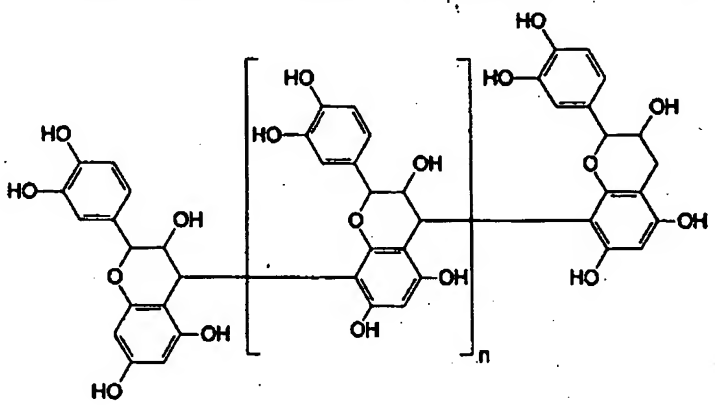
30. (original) The method of claim 29, wherein detecting comprises detecting a precipitate comprising the complex.

31. (original) The method of claim 29, wherein detecting the macromolecular complex between the hop bract tannin and the Stx comprises detecting an electrophoretic pattern associated with the presence of the macromolecular complex in the sample.

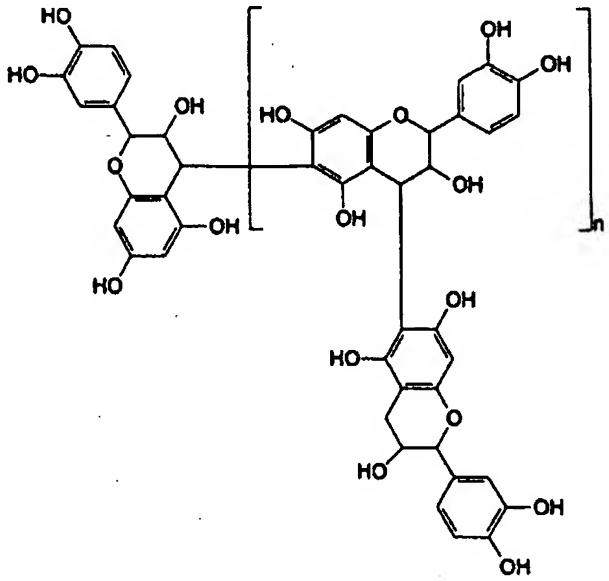
32. (original) The method of claim 29, wherein the hop bract tannin serves as a bioreceptor of a biosensor and detecting comprises measuring a change in a property of a transducer of the biosensor.

33. (original) The method of claim 29, wherein the hop bract tannin is a polycatechin between a 10-mer and a 30-mer.

34. (original) The method of claim 29, wherein the polycatechin has the forumla



where n = 8 to 28, or



where n = 8 to 28.

35. (original) The method of claim 29, wherein the hop bract tannin comprises a fraction isolated from a hop bract extract.

36. (original) The method of claim 35, wherein the fraction has a weight-average molecular mass between 5kDa and 30 kDa.

37. (currently amended) A method for isolating and purifying Stx-binding polyphenols, comprising:

contacting a mixture comprising [an]a Stx-binding polyphenolic compound isolated from *Humulus lupulus* with an Stx to form a macromolecular complex between the compound and the Stx;

isolating the macromolecular complex; and

separating the polyphenolic compound from the macromolecular complex to obtain a purified sample of the polyphenolic compound that binds Stx.

38. (original) The method of claim 37, wherein the Stx is coupled to an activated chromatographic matrix.

39. (original) The method of claim 37, wherein the Stx comprises he bioreceptor of a biosensor.

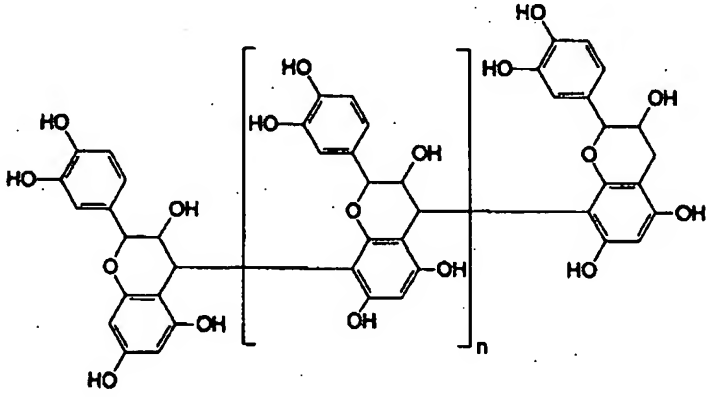
40. (original) The method of claim 38, wherein the Stx is Stx1.

41. (original) A method for prophylatic or post-exposure treatment of an inhaled Stx comprising administering a therapeutically effective amount of hop bract tannin intranasally to a subject.

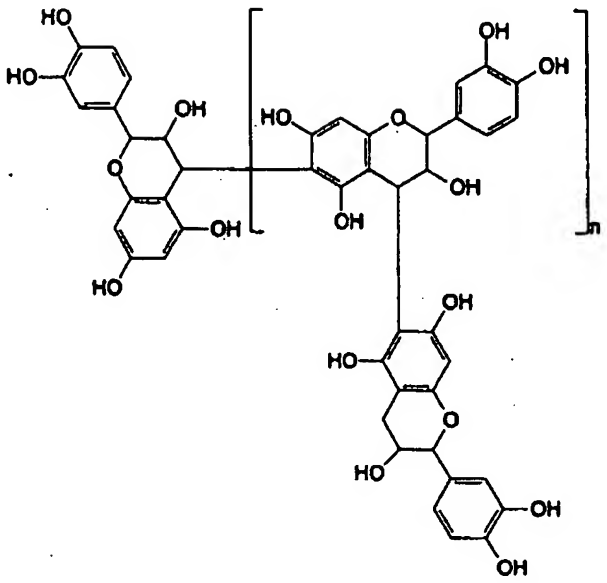
42. (original) A biosensor, comprising:
a hop bract tannin as a bioreceptor, and
a transducer.

43. (original) The biosensor of claim 42, wherein the hop bract tannin is a polycatechin between a 10-mer and a 30-mer.

44. (original) The method of claim 43, wherein the polycatechin has the forumla



where n = 8 to 28, or



where n = 8 to 28.

45. (original) The method of claim 42, wherein the hop bract tannin comprises a fraction isolated from a hop bract extract.

46. (original) The method of claim 45, wherein the fraction has a weight-average molecular mass between 5kDa and 30 kDa.

47.-57. (canceled)

58. (original) A method for neutralizing a bacterial toxin, comprising:
providing a hop bract tannin; and
contacting the bacterial toxin with the hop bract tannin to neutralize the toxin.

59. (original) The method of claim 58, wherein the bacterial toxin is selected from the group consisting of Shiga toxins and cholera toxins.

60. (original) The method of claim 58, wherein the hop bract tannin comprises a subfraction having a weight-average molecular weight from 5 kDa to 30 kDa.

61. (original) The method of claim 58, wherein the hop bract tannin comprises a polycatechin selected from the group of 10-mers to 30-mers, and mixtures thereof.

62. (original) An isolated polyphenolic component of a high molecular weight fraction of a hop bract extract, the high molecular weight fraction having a weight average molecular weight of greater than 5 kDa.

63. (original) A subfraction of a high molecular weight fraction of a hop bract extract, the high molecular weight fraction having a weight average molecular weight of greater than 5 kDa.

64. (original) The subfraction of claim 63, wherein the subfraction has a weight average molecular weight range selected from the group consisting of 5 kDa-30kDa, 5kDa-10kDa, 5kDa-8kDa, 8kDa-30kDa, 8kDa-10kDa and 10kDa-30kDa.

Remarks

By this Amendment the specification has been amended to reflect prior related applications and to add an abstract on a separate page.

Claims 16, 26, 28 and 47-57 have been canceled, solely to reduce the filing fee and not for reasons of patentability. Claim 25 was inadvertently not included in the parent PCT application. To conform with the requirements of U.S. patent practice, claim 25 is indicated to be canceled. Claims 22 and 37 have been amended to correct matters of form. Claim 17 has been amended to be in dependent form, solely to reduce the filing fee.

The present application is being filed with a reduced filing fee under 37 CFR 1.492(a)(4), because the international preliminary examination fee was paid to the United States Patent and Trademark Office, and the international preliminary examination report (IPER) stated that the criteria of novelty, inventive step (non-obviousness), and industrial applicability, as defined in PCT Article 33(1)-(4), have been satisfied for all the claims presented in the application entering the national stage. As the claim amendments were made solely to reduce the filing fee, and to correct matters of form, Applicants believe that they are entitled to the reduced fee. If the United States Patent and Trademark Office determines that the standard filing fee is due, please charge this fee to Deposit Account No. 02-4550.

No new matter has been added by this Amendment.

Conclusion

If any minor matters remain to be resolved before examination of this application, please call the undersigned at the telephone number listed below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By _____
Susan Alpert Siegel, Ph.D.
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ABSTRACT

FACTORS THAT BIND INTESTINAL TOXINS

Methods for neutralizing bacterial toxins such as Shiga toxins and cholera toxins are disclosed. In a particular embodiment, a method is provided for treating a subject suffering from an infection caused by an Stx-producing organism by administering a therapeutically effective amount of a hop bract tannin obtained from *Humulus lupulus*. Also provided are methods for isolating polyphenolic compounds that bind Stx molecules, and methods for detecting the presence of Stx molecules in a biological sample. In a disclosed embodiment, a subject infected with a Shiga toxin-producing *E. coli* strain is treated by enterically administering a high molecular weight fraction of hop bract extract to the subject.